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| 09/888,035 | 06/22/2001 | Atsunori Fukuda | SPO-115C1 | 9222 |

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EXAMINER

COLLINS, CYNTHIA E

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1638

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 09/888,035 | Applicant(s) FUKUDA ET AL. | |
| | Examiner Cynthia Collins | Art Unit 1638 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P **riod for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
 4a) Of the above claim(s) 10-13, 26 and 27 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 4, 6, 7, 14-17 and 24 is/are allowed.
- 6) ☒ Claim(s) 2-3, 5, 8-9, 18-23, 25, 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Amendment filed September 22, 2003 has been entered.

Claims 1-8, 14, 18-19, 23-25 and 28 are currently amended.

Claims 1-28 are pending.

Claims 10-13 and 26-27 are withdrawn from consideration.

Claims 1-9, 14-25 and 28 are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Claim Rejections - 35 USC § 112

Claim 28 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a rejection for the introduction of new matter.

Claim 28 as amended is drawn to an isolated nucleic acid molecule that is at least 15 nucleotides long and that is 96% or more homologous to an at least 15-nucleotide fragment of SEQ ID NO:1. The limitation "96% or more homologous to an at least 15-nucleotide fragment of SEQ ID NO:1" does not find support in the specification as originally filed, and thus constitutes new matter.

Claims 2, 3, 5, 8, 9, 19-23, 25 and 28 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed May 19, 2003.

Applicant's arguments filed September 22, 2003, have been fully considered but they are not persuasive.

Applicant argues that the invention is adequately described as a consequence of the incorporation of language related to specific hybridization under highly stringent conditions which the Office has indicated would yield structurally similar DNAs. Applicant additionally points to the incorporation of language reciting that the number of amino acids altered are 20 or less, resulting in sequences having alterations within 5% of the reference sequence. Applicant argues that the invention is adequately described due to the requirement that the variant sequences have a specific activity and at least 95% sequence identity to a reference sequence, which the Office has indicated would not have substantial variation (reply pages 8-9).

The rejection is maintained because the claims do not require that the variant or hybridizing sequences have a specific activity, as the recitation in the preamble that the isolated DNA "encodes an Na⁺/H⁺ antiporter" does not limit the variant or hybridizing sequences to sequences encoding proteins having an Na⁺/H⁺ antiporter activity. The rejection is also maintained because the requirement that the DNA encode a protein comprising the amino acid sequence of SEQ ID NO:2 wherein the number of amino acids that are substituted, deleted,

inserted and/or added is 20 or less is not equivalent to requiring that the DNA encode a protein having 95% sequence identity to SEQ ID NO:2, as the rejected claim language requires a specific number and type of changes be made to the amino acid sequence of SEQ ID NO:2. The rejection is additionally maintained because Applicant has not established that procedures for making variants of SEQ ID NO: 2 wherein the number of amino acids that are substituted, deleted, inserted and/or added is 20 or less and wherein the variants retain their activity are conventional in the art.

Claims are 18 and 23 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed May 19, 2003.

Applicant's arguments filed September 22, 2003, have been fully considered but they are not persuasive.

Applicant argues that the rejection should be withdrawn because the claims as amended require that the progeny carry the claimed DNA (reply page 9).

The rejection is maintained because it is unclear whether the claims as amended require that the progeny carry the claimed DNA (see the rejection of claims 18 and 23 under 35 U.S.C. 112, second paragraph, *infra*). The claims as amended require that "said transformant plant" carry the claimed DNA. It is unclear whether "said transformant plant" refers to the

parental transformant plant, or the transformant plant that is the offspring or clone of the parental transformant plant. Accordingly the rejection is maintained.

Claims 2, 3, 5, 8, 9, 19-23, 25 and 28 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated DNA of SEQ ID NO:1 or an isolated DNA encoding the amino acid sequence of SEQ ID NO:2, and vectors, cells and plants comprising said DNA, does not reasonably provide enablement for a DNA encoding the amino acid sequence of SEQ ID NO:2 wherein the number of amino acids that are substituted, deleted, inserted and/or added is 20 or less. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record set forth in the office action mailed May 19, 2003.

Applicant's arguments filed September 22, 2003, have been fully considered but they are not persuasive.

Applicant argues that one skilled in the art could practice the full scope of the claimed invention without undue experimentation because the specification discloses a working example of a single species that is representative of the genus of variants claimed, and because the specification also provides substantial guidance for making and using embodiments of the claimed invention, as well as a description of a representative number of species encompassed by the claimed genus (reply page 10).

The rejection is maintained because the specification does not provide sufficient guidance for one skilled in the art to practice the full scope of the claimed invention without undue

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experimentation. The disclosed working example combined with the general knowledge in the prior art regarding the making of sequence variants does not provide sufficient guidance for making and using the claimed variants, because the effect of even a single amino acid substitution, deletion, insertion or addition on a particular protein's function is unpredictable, and because the specification provides no guidance with respect to which amino acids of SEQ ID NO:2, if any, may be substituted, deleted, inserted or added without affecting its Na⁺/H⁺ antiporter function. Absent such guidance one skilled in the art would have to resort to making and testing variants on a trial and error basis in order to distinguish between operative and inoperative embodiments of the numerous variants that fall within the scope of the claims. Furthermore, as discussed *supra*, the specification does not describe a representative number of species encompassed by the claimed genus.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 18 and 23 are indefinite in the recitation of "wherein said transformant plant carries said DNA" at the end of the claims. It is unclear whether "said transformant plant" refers to the parental transformant plant, or the transformant plant that is the offspring or clone of the parental transformant plant. Amendment of the claims to indicate that the offspring or clone

carries the DNA of SEQ ID NO:1 or a DNA encoding SEQ ID NO:2 or the DNA encoding the Na⁺/H⁺ antiporter would overcome the rejection.

Claim Rejections - 35 USC § 102

Claims 18 and 23 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hiei et al. (The Plant Journal, 1994, Vol. 6, No. 2, pages 271-282), for the reasons of record set forth in the office action mailed May 19, 2003.

Applicant's arguments filed September 22, 2003, have been fully considered but they are not persuasive.

Applicant argues that Hiei et al. do not disclose the claimed subject matter because Hiei fails to disclose any relationship between GUS and SEQ ID NOS: 1 and 2. Applicant also argues that there is no motivation or suggestion to modify the teachings of Hiei et al. to arrive at the claimed subject matter (reply pages 11-13).

The rejection is maintained because it is unclear whether the claimed transgenic progeny plants comprise SEQ ID NOS: 1 and 2 (see the rejection of claims 18 and 23 under 35 U.S.C. 112, second paragraph, *supra*). Accordingly, the claimed invention is anticipated by, or in the alternative, is obvious in view of any prior art that teaches transgenic plants. Because Hiei et al. teach transgenic plants, and because the rejected claims do not set forth specific characteristics that distinguish the claimed transgenic progeny plants from the transgenic plants taught by Hiei et al., the burden of proof is upon the Applicant to show an unobvious distinction between the claimed plant and the plant of the prior art. See *In re Best*, 562, F.2d 1252, 195

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USPQ 430 (CCPA 1977). Amendment of the claims to indicate that the offspring or clone comprises an isolated DNA of SEQ ID NO:1 and/or an isolated DNA encoding SEQ ID NO:2 would overcome the rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Remarks

Claims 1, 4, 6, 7, 14-17 and 24 are allowed.

Claims 1-9, 14-17, 19-22, 24-25 and 28 are deemed free of the prior art, given the failure of the prior art to teach or suggest isolated nucleic molecules comprising SEQ ID NO:1 or

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encoding SEQ ID NO:2, or sequences that hybridize to SEQ ID NO:1 under highly stringent conditions, or sequences that encode a protein as described in SEQ ID NO:2 in which the number of amino acid substitutions, deletions, insertions and/or additions is 20 or less, or cells and plants transformed therewith.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180

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